



Policy regarding impartiality

HTCert performs certifications in accordance with national, european and international standards, conformity assessment of medical devices according to Regulation (EU) 2017/745 and surveillance activities for certificates issued under Directive 93/42/EEC.

The certification services are available to all customers and are applied without discrimination.

Decisions for granting, refusing, maintaining of certification, expanding or reducing the scope of certification, renewing, suspending or restoring, or withdrawing of certification are based on objective proofs of conformity or nonconformity.

HTCert commits itself to impartiality in the conduction of its certification activities and ensures that any conflicts of interest are identified, analyzed and eliminated, so that the objectivity of its certification activities is fulfilled at all times

In order to ensure strict neutrality and independence, HTCert

- does not offer or provide any consultancy services or any other service that creates a threat to impartiality
- is not linked to any organization which itself provides consultancy services
- is not involved in the development, production, installation, sale or maintenance of products
- is not involved in establishing, implementing or maintaining management systems
- does not carry out internal audits to its clients
- does not link rewards for top managers, evaluation staff and external personnel involved in evaluation activities with evaluation results
- makes the declarations of interest of top-level management publicly available
- has established an Impartiality Committee that consists of representatives from all interested parties and whose main function is to ensure the impartiality in compliance with ISO/IEC 17021:2015 and ISO/IEC 17065:2012. This committee meets annually to conduct a review of the impartiality of the assessment and certification processes.

Top management ensures that this policy is

- adequately documented, developed and updated
- communicated to all personnel to ensure awareness of their obligations
- accessible to all stakeholders
- subject to periodic reviews to ensure that it remains valid and appropriate

A multi-level system of written statements for compliance to impartiality principles of HTCert and mechanisms for their verification are applied to ensure full compliance of top management and all personnel with this policy.